510(k) Summary
LuxIR Handpiece

K070298

This 510(k) summary is being submitted in accordance with 21 CFR 807.92

1. SUBMITTER'S INFORMATION

NAME: Palomar Medical Technologies, Inc.

JUL - 3 2007

ADDRESS: 82 Cambridge Street
Burlington, MA 01803
Phone: (781) 993-2300
Fax: (781) 993-2330

CONTACT: Sharon Timberlake, RAC, CCRA
Director of Regulatory Affairs

DATE PREPARED: June 11, 2007

2. DEVICE INFORMATION

TRADE/PROPRIETARY NAME: Palomar LuxIR Handpiece

COMMON/USUAL NAME: Infrared Handpiece

CLASSIFICATION NAME: Laser surgical instrument
21 CFR §878.4810
Infrared therapeutic heating lamp
21 CFR §878.4810

PRODUCT CODE: GEX, ILY

3. PREDICATE DEVICES

StarLux LuxIR Handpiece
Palomar Medical Technologies, Inc.
(K060069 & K050370)

4. INTENDED USE

The LuxIR is intended for photocoagulation of soft tissue in dermatologic applications. It also provides topical heating for the purpose of elevating tissue temperature for the temporary relief of minor muscle and joint pain and stiffness, the temporary relief of minor joint pain associated with arthritis, the temporary increase in local circulation where applied, and the relaxation of muscles. In addition, it may also help muscle spasms, minor sprains and strains, and minor muscular back pain.

5. DEVICE DESCRIPTION

The LuxIR Handpiece is an accessory to the StarLux™ Pulsed Laser and Light System. The complete StarLux Pulsed Light System consists of a cart, system console, chiller, a footswitch, and a handpiece. The Palomar LuxIR Handpiece emits energy in the infrared wavelength.

6. PERFORMANCE DATA

The review of the performance data provided in this notification demonstrates that the modified LuxIR Handpiece is substantially equivalent to its predicate device.

7. SUBSTANTIAL EQUIVALENCE

The modified LuxIR Handpiece was found to be substantially equivalent to its predicate device because it shares identical indications for use, substantially similar technical characteristics, and operation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 3 2007

Palomar Medical Technologies, Inc.
% Ms. Sharon Timberlake, RAC, CCRA
Director, Regulatory Affairs
82 Cambridge Street
Burlington, Massachusetts 01803

Re: K070298
Trade/Device Name: Palomar LuxIR Handpiece
Regulation Number: 21 CFR 878.4810400
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: June 11, 2007
Received: June 12, 2007

Dear Ms. Timberlake:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K070298

Device Name: Palomar LuxIR Handpiece

Indications for Use:

The LuxIR Handpiece is intended for:

- Photocoagulation of soft tissue in dermatologic applications.
- Provide topical heating for the purpose of elevating tissue temperature for the temporary relief of minor muscle and joint pain and stiffness, the temporary relief of minor joint pain associated with arthritis, the temporary increase in local circulation where applied, and the relaxation of muscles. In addition, it may also help muscle spasms, minor sprains and strains, and minor muscular back pain.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K070298

Prescription Use __X___ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)